

ERIC F. GREENBERG, P.C.
A professional corporation

December 20, 2004

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket Nos. 1996P-0418, 1997P-0197, 1998P-0203, and 2000N-0504 and RIN
number 0910-AC14: Comments of Egg Fusion, Inc.

To the FDA:

On behalf of Egg Fusion, Inc. 655 Deerfield Road, Suite 100, Deerfield, Illinois, 60015,
we are writing to comment on the Food and Drug Administration's proposed rule on
controlling *Salmonella enteritidis* (SE) in shell eggs. While we generally support the
agency's efforts, we believe they could be improved by automating the record keeping
requirements and through additional measures to increase track-and-trace capabilities
beginning at the farm level.

Automating record keeping¹

Pursuant to the Paperwork Reduction Act of 1995, FDA requested comments on: 1)
ways to enhance the quality, utility, and clarity of the information to be collected; and 2)
ways to minimize the burden of the collection of information on respondents, *including*

¹ Egg Fusion recognizes that FDA sought comments specifically directed to the information collection provisions by October 22, 2004. Because we believe the concepts discussed in these comments promote both egg safety and enhanced information technology, we encourage FDA to consider these comments in connection with its development of both the information collection components and substantive egg safety provisions of the proposals. A copy of these comments has been submitted to OMB.

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[emphasis added] We encourage FDA to incorporate an automated record keeping requirement into the proposed rule. An automated system and equipment would enhance and support the record keeping requirements outlined in the proposed rule in an efficient, effective manner. An appropriately scoped system would allow for easy access to information on a farm's quality assurance and preventive measures performance. The system could provide farm-specific data, and an efficient, cost-effective way to research compliance. Because the system is automated, it would greatly reduce the burden placed upon egg producers as well as the time, frequency and cost associated with FDA inspections.

Tracking-and-Tracing

While the FDA's record keeping objective is focused on the plans and testing activities of the producers' SE initiatives, we believe the automation of this data coupled with tracking and traceability at an individual egg level can bring great value to the FDA and consumers alike.

Various technologies exist today for marking individual eggs primarily for the purposes of freshness dating. If FDA's objective is to significantly reduce, if not eliminate, SE and its physical and economic effects, it should implement a requirement for on-egg dating and traceability. The individualized coding of eggs allows a level of record keeping sophistication that is not possible using the measures in practice or currently proposed by FDA. In addition to adding levels of detail to the records kept by producers, such a

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process will improve the ability of FDA, the producers, and any other concerned entity, to investigate the source and scope of any outbreak. The related record keeping database will enhance exponentially the producers' ability to seek correlations between specific parameters and outbreaks, and thereby improve producers' ability to reduce future contamination.

Egg Fusion believes that FDA is missing an opportunity to affect the long-term safety of the egg supply if it does not incorporate a track-and-trace requirement in the current proposed rule. Such a traceability system will assist in the containment of contamination and outbreaks, and through research of data related to SE positive eggs, it can help prevent future infection and outbreaks.

Overall, the purpose of the Egg Safety Action Plan is to attain a reduction in the number of SE contaminations and infections. With a system of appropriate depth such as an automated record keeping mechanism, researchers can use environmental and other data associated with SE contaminated eggs to learn more about infection/contamination-promoting environments and scenarios. Preventive measures can then be tailored to more effectively eliminate or reduce potential contamination or spread of SE.

Addressing multiple concerns

Indeed, as the industry faces a future of continuing concerns over microbial outbreaks as well as potential bioterror-inspired food supply tamperings, FDA, egg producers, and

numerous other entities are likely to be under increased pressure to incorporate better record keeping methodologies, as well as track-and-trace technology, in order to limit the injuries and other damages caused by outbreaks and tamperings, and to investigate, gather and assess data on outbreaks or contaminations.

Further, in adopting this strategy, it will be important to require a system that produces a permanent and tamper proof traceability code so that there is no doubt about the integrity and security of the product. For example, available laser technology uses a commercial NEMA-rated continuous wave Co2 gas laser emitting infrared light. The laser light ablates the egg shell to produce an etching effect. The system requires no physical contact with eggs, as it is installed on and interfaced with egg grading equipment. Egg Fusion's system incorporates this technology.

Traceable coding

The traceable code on an egg allows for the capture, database and storing of associated life cycle information of an individual egg. This information could be utilized at many stages along the farm-to-table continuum to contain outbreaks and prevent future SE infection and outbreaks. Attachment 1 illustrates the farm to consumption lifecycle and demonstrates how an automated, individual egg-marking system, such as Egg Fusion's, can capture information about an individual egg's history from creation, through processing, packaging and distribution.

Automated record keeping

As noted, Egg Fusion encourages FDA to consider incorporating an automated record keeping requirement into the proposed rule. The record keeping requirements set forth in the proposed rule can be addressed and enhanced with the use of an automated system.

An automated system can provide a greater degree of organization to collected information. Data is more easily accessible and a collective database allows for efficient correlation of individual data points. Automated systems may also be more accurate than traditional paper record keeping systems.

Currently, the proposed rule calls for the egg producer to maintain records only on environmental and egg testing, and diversion of positive-testing eggs from the table egg market.

An appropriate tracking and tracing system can collect this type of information, and it can also provide an abundance of additional individual-egg data, such as: egg origin and processing; pack date; grader and pack lane; environmental data; customer data; hen house; and hen house type. An automated, comprehensive data system provides egg producers with an abundance of information, much more than that garnered by spot environmental and egg testing, and the system's traceability coding eases the burden of any necessary egg diversion.

Database stored information can be used by producers and regulators to prevent future outbreaks. This benefit is achieved by correlating information from many farms and that can only be done expeditiously with an automated system. The information can be analyzed to determine environmental and other factors associated with outbreaks, and may serve as a mechanism to distinguish naturally-occurring outbreaks from deliberate attacks.

Paper-based or electronic records permissible

Finally, Egg Fusion interprets FDA's proposed record keeping requirements as permitting either paper-based records or electronic records. Therefore, a producer would be in compliance with the proposed requirement if it utilized an electronic record keeping system that met the requirements of the proposal.

Should FDA choose not to require automated record keeping at this time, we suggest that FDA clarify, in the proposed rule text or preamble, that either electronic systems or paper systems would be in compliance with the proposed record keeping requirement.

Summary

In summary:

1. Egg Fusion believes the preventive measures in the proposed rule could be improved by automating the record keeping requirements and through additional measures to increase track-and-trace capabilities beginning at the farm level;

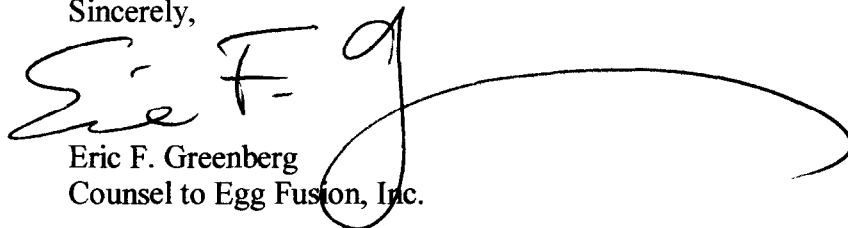
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2. We urge FDA to implement a track-and-trace requirement in addition to the preventive measures set forth in the proposed rule;
3. We encourage FDA to consider incorporating an automated record keeping requirement into the proposed rule; and,
4. Should FDA choose not to require automated record keeping at this time, we request that FDA clarify, in the proposed rule text or preamble, that either electronic systems or paper systems would be in compliance with the proposed record keeping requirement.

Thank you for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read 'Eric F. Greenberg', with a long, sweeping horizontal line extending to the right.

Eric F. Greenberg
Counsel to Egg Fusion, Inc.

EFG/dmw

cc: Office of Management and Budget, via facsimile on 202-395-6974,
Attn: Desk Officer for FDA.

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Attachment 1

